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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,911	02/16/2001	Leonard C. Harrison	13406	5393

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,911

Applicant(s)

HARRISON ET AL.

Examiner

Daniel Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, drawn to a method of making insulin secreting colonies of pancreatic cells comprising bone morphogenetic protein (BMP), laminin-1 or laminin-1-containing extracellular matrix or functional derivatives, homologues, mimetics, analogues or agonists thereof in the presence or absence of antagonists of TGF- β 1 or Activin A, classified in class 435, subclass 377.
- II. Claims 23-25, drawn to a method of treating Type 1 diabetes or a related condition comprising transplanting insulin-secreting cells produced following *in vitro* culture in the presence of BMP, laminin-1 or laminin-1-containing extracellular matrix or functional derivatives, homologues, mimetics, analogues or agonists thereof, classified in class 424, subclass 562.
- III. Claims 26 and 27, drawn to a method of treating Type 1 diabetes or a related condition comprising administering BMP or a heterodimer formed from two or more BMPs or derivatives, homologues, mimetics, analogues and/or agonists thereof, classified in class 424, subclass 426.
- IV. Claims 28 and 29, drawn to a method of treatment or prophylaxis of islet/ β cell hyperplasia adenoma or a related condition including pancreatic cancer comprising administering a BMP, classified in class 424, subclass 426.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of making insulin secreting cells and methods of treating various conditions stemming from defects of insulin secreting cells. Although inventions I and II are related in that the products made by the method of invention I could be used in the method of invention II, the methods per se cannot be used together. Furthermore, the insulin-secreting cells used in invention II could be obtained by means other than the method of invention I (e.g. isolation of insulin-secreting cells from pancreatic tissue). Although inventions III and IV are drawn to methods that utilize the same agonist and antagonist compounds as are used in invention I, the methods cannot be used together and the mode and purpose of administration of the compounds according to invention I is distinct in the mode and purpose of administration according to inventions III and IV.

Inventions II and III-IV are also unrelated. Although the inventions are all drawn to methods of treating various conditions stemming from defects of insulin secreting cells, the method of invention II comprises administering insulin-secreting cells while inventions III and IV comprise administration of agonists or antagonists that affect the function of insulin secreting cells. These inventions are not disclosed as capable of use together. In fact, it can be argued that the method of invention IV would reduce the probability of successful treatment if used in combination with the method of invention II and thus the inventions are mutually exclusive.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Finally, inventions III and IV are unrelated because the methods are drawn to the use of different compound to treat different conditions. And, the methods of the claimed inventions are mutually exclusive in that the compounds used are antagonistic to one another and would therefore decrease the effectiveness of the treatment if given in combination.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is also reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
June 4, 2002



**JAMES KETTER
PRIMARY EXAMINER**